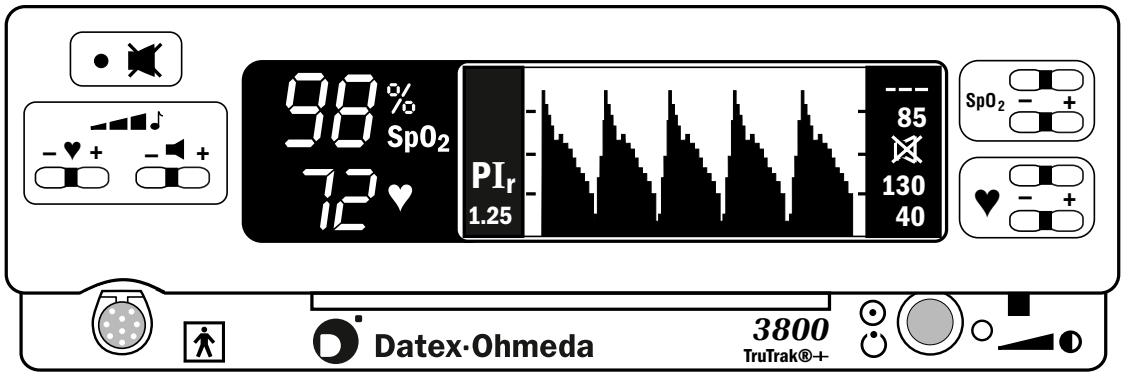
3800 Pulse Oximeter

TruTrak®+

User's Manual



6050-0006-380
Printed in USA

Important

This device performs as described in this manual, and in accompanying labels and inserts, when assembled, operated, maintained, and repaired in accordance with the instructions provided.

Attention! Consult the accompanying instructions before using this device.

The safety, reliability, and performance of this device can be assured only under the following conditions:

- If it is used according to the accompanying operating instructions.
- If fittings, extensions, readjustments, changes, or repairs are carried out by agents authorized by Datex-Ohmeda.
- If it is used in buildings having ground equalization wiring that complies with relevant local standards and regulations.

CAUTION: US Federal law restricts this device to sale by or on the order of a licensed medical practitioner. Outside the USA, check local laws for any restriction that may apply.

This device must be cleaned and checked periodically. Do not use a defective device. Parts that are broken, missing, plainly worn, distorted, or contaminated should be replaced immediately. If repair or replacement becomes necessary, request service advice from Datex-Ohmeda (information is listed on the back cover). Do not repair this device or any of its parts other than in accordance with written instructions provided by Datex-Ohmeda.

The user of this device shall have the sole responsibility for any malfunction that results from improper use, faulty maintenance, improper repair, unauthorized service, damage, or alteration by anyone other than Datex-Ohmeda.

Trademarks

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All other product and company names are the property of their respective owners.

Text revised: October 2002

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1/Overview

This chapter

- Introduces the product, including the principles of its operation.
- Describes the oximeter's controls and features.
- Lists the precautions you must take when using the oximeter.

Product description

The Datex-Ohmeda Model 3800 pulse oximeter with TruTrak®+ technology features two easy-to-read displays that present patient data and status information.

- The numeric display shows the SpO_2 and pulse rate values.
- The graphic display shows the plethysmographic waveform, messages, the Relative Perfusion Index (PI_r™) pulsatile value, and the high and low alarm limit settings for SpO_2 and pulse rate.

Intended use

The 3800 pulse oximeter with TruTrak+ technology is indicated for spot-checking and continuous monitoring of functional oxygen saturation and pulse rate, including monitoring during conditions of clinical patient motion.[1] This device is intended for use with adult, pediatric, and neonatal patients in both hospital and non-hospital environments.

Important: Only Datex-Ohmeda OxyTip®+ sensors can be used with this monitor.

TruTrak+ technology

TruTrak+ technology improves pulse oximetry performance during conditions of clinical patient motion. In the clinical environment, oximetry readings are affected by several types of patient motion. The types of motion include clenching, pressing, and rubbing as well as extending, flexing, and kicking. Unlike motion technologies that use only a single method to correct for motion, TruTrak+ selects one of many proprietary motion-correction algorithms, depending on the type and intensity of the motion.

TruTrak+ technology employs a patented five-step process that consists of 1) high-speed data sampling; 2) motion identification, quantification, and

[1] *Anesthesia & Analgesia*. 2002;94,1S, S54-S60

correction; 3) calculation of the SpO_2 value; 4) weighting and averaging of the SpO_2 value; and 5) the display of an improved SpO_2 value. The result of this process is a more accurate and stable displayed SpO_2 value, with fewer false alarms or dashed displays.

Important: For TruTrak+ performance, the averaging mode must be set to Long. See *Setup* in chapter 2.

PI_r pulsatile value

The PI_r pulsatile value indicates the strength of the pulse signal at the sensor site: the higher the PI_r value, the stronger the pulse signal. A strong pulse signal increases the validity of SpO_2 and pulse rate data.

PI_r is a relative value that varies from patient to patient. Clinicians can use the PI_r value to compare the strength of the pulse signal at different sites on a patient in order to locate the best site for the sensor (the site with the strongest pulse signal).

You can choose to display or not display the PI_r value (see *Setup* in chapter 2).

Other features

- PerfTrak® waveform display, an automatic scale of the plethysmographic waveform to provide a relative indication of the sensor site perfusion level.
- Large SpO_2 digital display for clear differentiation from the pulse rate value.
- Backlit display and contrast control for excellent visibility in subdued lighting conditions; adjustable viewing angle, using the pull-down feet under the monitor.
- Direct access to user-selectable high and low alarm limits for SpO_2 and pulse rate.
- An audible pulse indicator with an adjustable volume; the automatic pitch modulation reflects changing SpO_2 level.
- Visual and audible (adjustable volume) alarms.
- An alarm-silence feature that silences audible alarms for 120 seconds.
- An all-mute feature that silences audible alarms until deactivated.
- Automatic tiered alarm messages.
- Short, medium, or long SpO_2 response averaging modes.
- Adult or neonatal patient modes for default pulse rate alarm settings.
- Automatic storage of up to 12 hours of SpO_2, pulse rate, and alarm limit violations data in trend memory, which can be output through the RS-232 serial connector.
- An automatic self-test and calibration check at start-up. After start up, the oximeter continuously performs background self-tests.
- Rechargeable, sealed, lead-acid battery operation, including battery status reporting.

Functional components

The 3800 oximeter uses the following key electrical component elements to determine SpO_2, pulse rate, and PI_r pulsatile values:

- The sensor
- Sensor-signal processing
- Microprocessor calculations

The sensor consists of

- The light source—red and infrared light-emitting diodes (LEDs)
- The photodetector—an electronic device that produces an electrical current proportional to incident light intensity

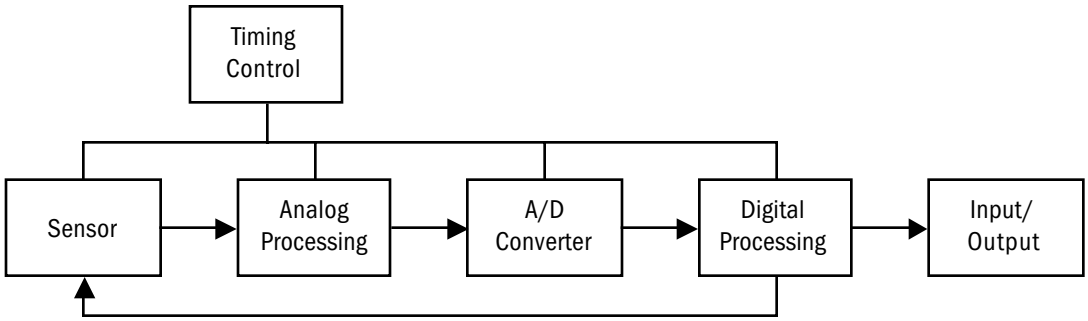


Figure 1-1. Signal processing block diagram

The two light wavelengths generated by the LEDs pass through the tissue at the sensor site. The photodetector collects this light (partially absorbed and modulated) and converts it into an electronic signal that is sent to the oximeter for further processing.

The electronic circuitry receives the photodetector's electronic signal, processes it, and passes it on to the microprocessor for calculation of the SpO_2, pulse rate, and PI_r pulsatile value.

Principles of operation

The 3800 pulse oximeter uses a two-wavelength pulsatile system—red and infrared light—to distinguish between oxygenated (O_2Hb) and reduced (HHb) hemoglobin, each of which absorbs different amounts of light emitted from the oximeter sensor. The system then calculates the relative percentage of these two constituents and displays SpO_2.

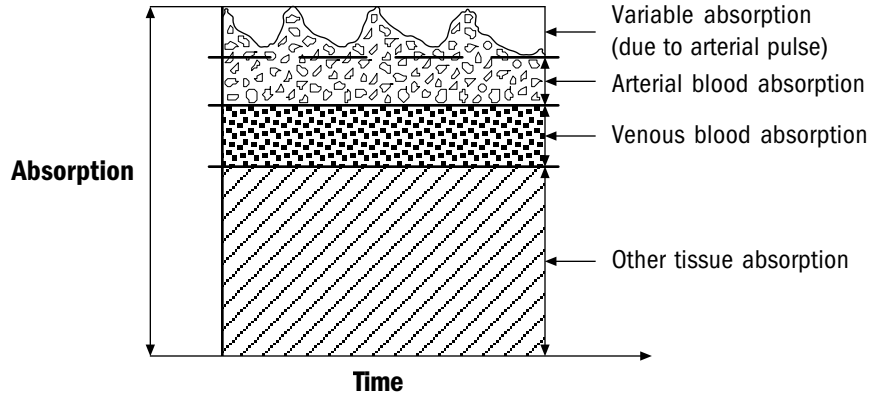


Figure 1-2. Comparative light absorption

Arterial blood pulsation at the test site modulates transmission of the oximeter sensor's light. Since other fluids and tissues present generally don't pulsate, they don't modulate the light passing through that location. The attenuation of light energy due to arterial blood flow is detected and isolated by using the pulsatile portion of the incoming signal. PI_r pulsatile value is a measure of the relative size of this portion of the signal.

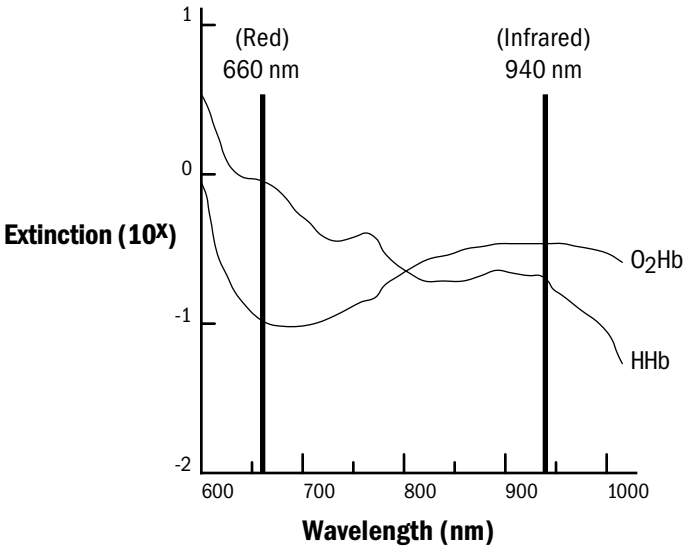


Figure 1-3. Extinction versus wavelength graph

The sensor's photodetector converts the light, which is partially absorbed and modulated as it passes through the tissue sample, into an electronic signal. Since O_2Hb and HHb allow different amounts of light to reach the photodetector at the selected wavelengths, the electronic signal varies according to the light source that

is “on” and the oxygenation of the arterial hemoglobin. Analog and digital signal processing then converts the light-intensity information into SpO_2, pulse rate, and PI_r pulsatile values for display on the monitor.

Calibration

A CO-oximeter typically uses four or more wavelengths of light and calculates reduced hemoglobin (HHb), oxyhemoglobin (O_2Hb), carboxyhemoglobin (COHb), and methemoglobin (MetHb). Datex-Ohmeda pulse oximeters use two wavelengths ranges, 650 nm - 665 nm and 930 nm - 950 nm, both with an average power of less than 1 mW. These wavelengths are used to calculate the presence of O_2Hb and reduced HHb. Because of this, pulse oximetry readings will be different than CO-oximetry readings in situations where a patient’s COHb or MetHb are increased.

Two different methods of calibration are currently used by manufacturers of pulse oximeters: *fractional* and *functional*.

Important: This pulse oximeter uses the functional calibration method. The user cannot change the calibration method to fractional.

- *Fractional* saturation is represented mathematically as the percentage of the total amount of hemoglobin carrying oxygen. It is determined by dividing the oxyhemoglobin by the total hemoglobin.

$$\text{Fractional } SpO_2 = \left(\frac{O_2Hb}{Hb_{TOTAL}}\right) \times 100 = \left(\frac{O_2Hb}{O_2Hb + HHb + COHb + MetHb}\right) \times 100$$

- *Functional* saturation is represented mathematically as the percentage of hemoglobin capable of carrying oxygen that is carrying oxygen.

$$\text{Functional } SpO_2 = \left(\frac{O_2Hb}{Hb_{TOTAL} - COHb - MetHb}\right) \times 100 = \left(\frac{O_2Hb}{O_2Hb + HHb}\right) \times 100$$

The calculation of SpO_2 assumes 1.6% carboxyhemoglobin (COHb), 0.4% methemoglobin (MetHb), and no other pigments. Appreciable variation from these values will influence SpO_2 accuracy. These values are based on the Datex-Ohmeda Pulse Oximeter Empirical Calibration Study.

Front panel

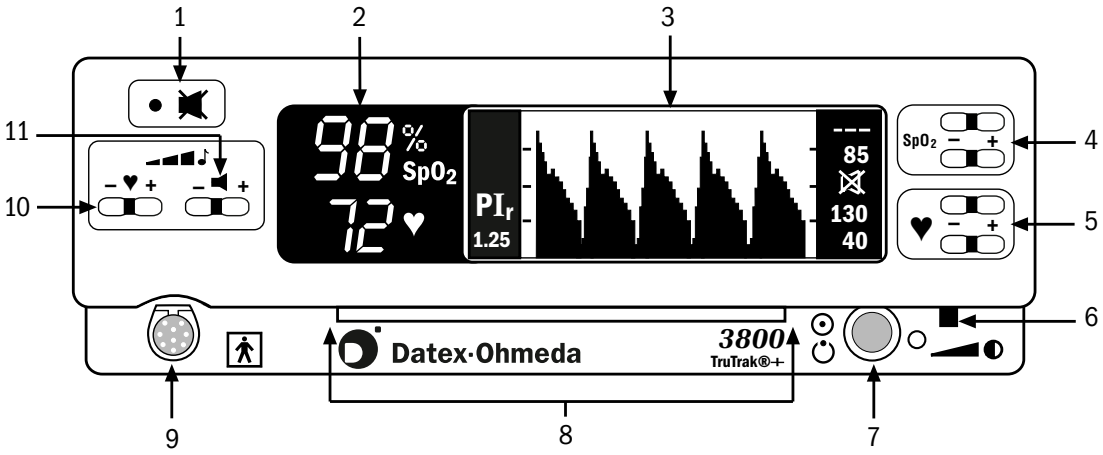
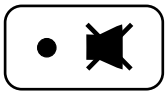


Figure 1-4. 3800 Pulse Oximeter front panel

1 Alarm silence button
2 Numeric display (LED)
3 Graphic display (LCD)
4 SpO_2 alarm limits, high/low setting buttons
5 Pulse rate alarm limits, high/low setting buttons
6 Display contrast adjust slide
7 Power/Standby button
8 Carrying handle
9 Sensor connector
10 Pulse beep volume button
11 Alarm volume button



1 Alarm silence button

This button has two functions:

- 120-second alarm silence—activated by a single press.
- Continuous all mute—activated by three quick presses (if the all-mute feature is enabled). Press once to deactivate.

Alarm silence

When an active alarm condition exists, press this button to silence the audible portion of the alarm for 120 seconds. The flashing red or yellow alarm light becomes a steady light. If an alarm condition still exists after 120 seconds, the audible tone and flashing light resume.

Exceptions: Both NO SENSOR and SENSOR OFF audible alarms will not be activated until after the unit obtains a valid signal. The same conditions apply to an active audible alarm for NO SENSOR, SENSOR OFF, or SENSOR FAILURE that has been silenced; i.e., once the sensor alarm condition is acknowledged by silencing the audible alarm, a new audible alarm will not sound until the condition has been cleared and the unit obtains a valid signal.

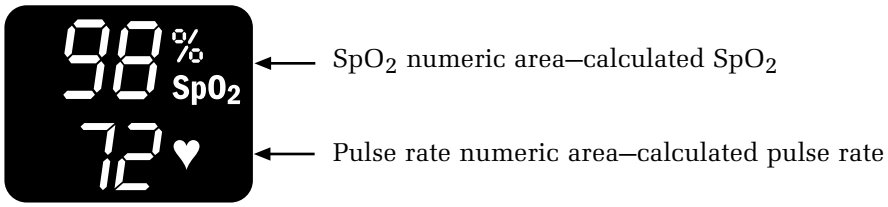
NOTE: Pressing the alarm silence button produces 120 seconds of silence, regardless of other alarm conditions that may occur during this 120-second interval, except for the SYSTEM FAILURE, CONNECT UNIT TO LINE POWER, and BUTTON STUCK alarms.

All mute

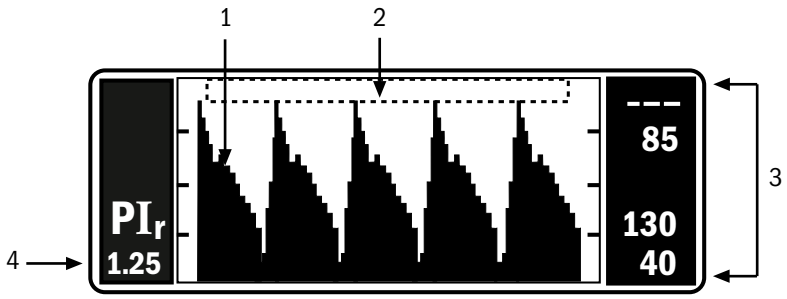
To continuously silence any alarm that can be silenced, press the alarm silence button three times within three seconds. After you have activated all mute, the all mute icon flashes between the SpO_2 and pulse rate alarm limit settings on the right side of the screen display. When an alarm condition occurs, the alarm button light flashes and the alarm message appears on the waveform display but no audible alarm sounds.

When all mute is active, press the alarm silence button once to deactivate this feature and enable all audible alarms.

2 Numeric display



3 Graphic display



1 Plethysmographic waveform

The PerfTrak waveform display appears after the monitor has detected data from the sensor. It represents the blood volume change of the hemodynamic system, assuming no other factors (e.g., motion artifact) are present. This waveform scales automatically to the perfusion level or strength of the signal being received at the patient monitoring site.

2 Message area

Status and alarm messages appear above the waveform area on the waveform display (the height of the waveform is reduced while messages are displayed). Status messages give you information about the oximeter's operating condition. Alarm messages alert you to conditions that need your attention. See chapter 3 for complete alarm and status message information.

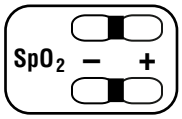
3 SpO_2 and pulse rate alarm limits

The high and low alarm limit settings appear here. If a limit is set to OFF, three dashes appear in the location for that limit.

When an SpO_2 or pulse rate limit is violated, the LED on the numeric display and the LCD's limit value flashes for that alarm.

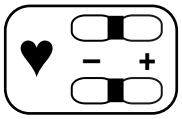
4 PI_r pulsatile value

Dashes (- - -) appear if the following conditions exist: no sensor is connected to the unit, the sensor is not attached to the patient, the sensor has failed, there is insufficient light penetrating the tissue site, or there is too much ambient light.



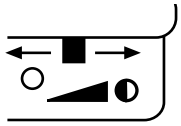
4 SpO_2 alarm limits, high and low

The top button sets the high alarm limit and the bottom button sets the low alarm limit. For either limit, press the + side of the button to raise the value or the – side to lower it. As you press one of these buttons, the values do not cycle through the available settings; e.g., when you reach 100, the value does not cycle (or wrap) to 50 or OFF.



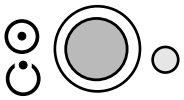
5 Pulse rate alarm limits, high and low

The top button sets the high alarm limit, the bottom button sets the low alarm limit. For either limit, press the + side to raise the value or the – side to lower it. As you press one of these buttons, the values do not cycle through the available settings; e.g., when you reach 235, the value does not cycle (or wrap) to 30 or OFF.



6 Display contrast adjuster

Use this sliding lever to adjust the vertical viewing angle of the graphic display Slide the lever to the left to reduce the contrast and to the right to increase it.



7 Power/Standby button/AC power light

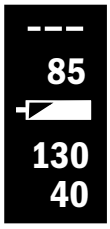
This button toggles between On (operational mode) and Off (standby mode). The battery recharges as long as the unit is plugged into the AC power supply. No displays are visible in the Off/Standby mode.

The green light to the right of the button is lit when the unit is connected to an AC power supply.

Battery operation

The oximeter runs for at least five and one-half hours on a new, fully charged battery at normal operating temperatures. LOW BATTERY appears when between 5 and 15 minutes of battery operation time remain. Plug the monitor into AC power to continue monitoring and recharge the battery. The unit will operate with a dead or defective battery when it is connected to the AC power supply.

When the CONNECT UNIT TO LINE POWER message appears, you must immediately plug the oximeter into the AC power supply or the unit turns itself off after 10 seconds.



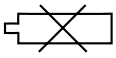
When operating on battery power, an icon appears between the two pairs of alarm limit values on the right side of the LCD. This icon indicates the battery condition as follows:

 Charged/not low

 Low

If the all mute condition exists, the display of this icon alternates with the display of the all mute icon.

This icon appears on the status screen:

 Depleted, not installed, or defective

8 Carrying handle

The lower front portion of the oximeter's case is designed to be a carrying handle for ease of moving the unit from one place to another.

9 Sensor connector

The sensors for this oximeter plug into this nine-contact connector. Use only Datex-Ohmeda sensors compatible with this oximeter (see *Parts list* in chapter 4).

10 Pulse beep volume button

This button adjusts the volume level for the pulse indicator in incremental steps from OFF to level 5 (default is 2). Press the + side of the button to increase the volume or the – side to decrease it; you will hear the volume level as you press the button. As you press one of these buttons, the values do not cycle through the available settings; e.g., when you reach 5, the value does not cycle (or wrap) to OFF.

As you adjust the volume, the volume setting is shown in the message area above the waveform.

NOTE: The pitch of the pulse tone changes as the SpO_2 value increases or decreases—the higher the SpO_2 value, the higher the pitch of the pulse tone.

11 Alarm volume button

This button adjusts the audible alarm volume level in incremental steps from 1 to 5 (default is 3). You cannot set the alarm volume to OFF. Press the + side of the button to increase the alarm volume or the – side to decrease it; you will hear the volume level as you press the button. As you press one of these buttons, the values do not cycle through the available settings; e.g., when you reach 5, the value does not cycle (or wrap) to 1.

As you adjust the volume, the volume setting is shown in the message area above the waveform.

Rear panel

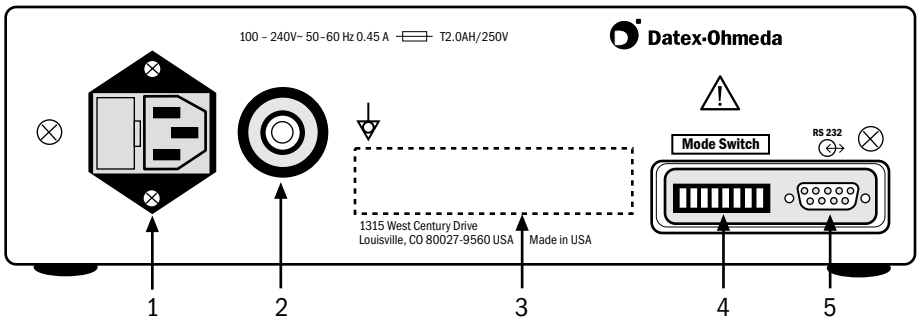


Figure 1-5. 3800 Pulse Oximeter rear panel

WARNING: Electrical shock hazard. Because the unit is not grounded when it is operating on battery power, do not connect any equipment to the RS-232 connector on the rear panel unless the unit is connected to the AC power supply.

1 Power entry module

This module contains

- Fuses
- Power connector for the power cord that connects the oximeter to the AC power supply for continuous operation and/or battery recharging.

2 Equipotential ground connector

In locations where this type of ground is required, connect your grounding system here.

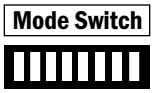
3 Product information label

The following symbols may appear on the monitor, on labels affixed to the monitor, and/or on shipping materials. Refer to *Compliance with standards* in Appendix A for definitions of symbols that indicate compliance with standards set by regulatory agencies.

CAUTION: US Federal law restricts this device to sale by or on the order of a licensed medical practitioner. Outside the USA, check local laws for any restriction that may apply.

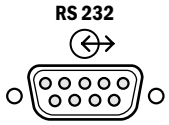
The serial number for this product appears as SN AAAYxxxxx. The first three letters are specific to the product type, the fourth letter indicates the year of manufacture (F=2002, G=2003, etc. “I” and “O” are not used.). The last five digits are the sequential number for the unit as produced in the indicated year.

The warranty expiration date for this product is printed near this symbol.



4 Mode Switch

This symbol identifies the two-position switches that set the display language, the averaging mode, the patient mode, the display of the PI_r pulsatile value, and the EMI line frequency. See chapter 2 for instructions.



5 RS-232 serial connector

This 9-pin connector provides serial digital information on SpO_2, pulse rate, alarm limit violations, and alarm messages. It is compatible with most RS-232 devices capable of accepting a 9600 baud input. See Appendix B for instructions.

Precautions

Two types of precautions appear in this manual: warnings and cautions.

- A **WARNING** indicates the possibility of injury to the patient or operator.
- A **CAUTION** indicates a condition that may lead to equipment damage or malfunction.

Warnings

Failure of operation

If the oximeter fails any part of the checkout procedures or current leakage test, remove it from operation until qualified service personnel have corrected the situation.

It is possible for any device to malfunction; therefore, always verify unusual data by performing a formal patient assessment.

Explosion hazard

Do not use the monitor in the presence of any flammable anesthetic mixture.

Electrical shock and flammability hazard

Before cleaning or servicing the oximeter, always turn it off and disconnect the power cord from the AC power supply.

Electrical shock hazard

Do not remove the monitor cover. An operator may perform only maintenance procedures specifically described in this manual. Refer servicing to qualified service personnel trained in the repair of this equipment.

Measure the oximeter's leakage current whenever an external device is connected to the RS-232 port. Forward and reverse polarity = 100 microamperes maximum.

This equipment must be properly grounded.

- Electrical safety specifications (e.g., current leakage and ground resistance) can be assured only when the monitor is connected to a three-wire, grounded receptacle without the use of extension cords or adapters.
- If there is any doubt about the integrity of the AC power supply protective earth conductor, operate the monitor on internal battery power.
- Because the unit is not grounded when it is operating on battery power, do not connect any equipment to the RS-232 connector on the rear panel unless the unit is connected to the AC power supply.

Data validity

Conditions that may cause inaccurate readings and impact alarms include interfering substances, excessive ambient light, electrical interference, excessive motion, low perfusion, low signal strength, incorrect sensor placement, poor sensor fit, and movement of the sensor on the patient.

To prevent erroneous readings, do not use an inflated blood pressure cuff or arterial blood pressure measurement device on the same limb as the oximeter sensor.

Patient safety

The correct use of the oximeter is to measure only arterial oxygen saturation (SpO_2), pulse rate, and Relative Perfusion Index pulsatile value.

- A pulse oximeter does not measure respiration and should never be used as a substitute for an apnea monitor or as the primary monitor for infants being monitored for apnea.
- A pulse oximeter may be used during sleep studies of adults only to gather information regarding SpO_2, pulse rate, and PI_r pulsatile value.

This device is not intended for use in a magnetic resonance imaging (MRI) environment.

Patient safety (sensors)

Patient conditions (such as reddening, blistering, skin discoloration, ischemic skin necrosis, and skin erosion) may warrant changing the sensor site frequently or using a different style of sensor.

To prevent patient injury or equipment damage, use only Datex-Ohmeda oximeter sensors approved for use with this oximeter. For complete information about the safe and appropriate use of a sensor, consult the instructions for that sensor.

Discard a damaged sensor immediately. Do not repair a damaged sensor or use a sensor repaired by others.

RS-232 system interconnection

Accessory equipment connected to the RS-232 serial connector must be certified according to the current version of the respective IEC/EN standards (e.g., IEC 60950 for data processing equipment and IEC/EN 60601-1 for medical equipment). All configurations shall also comply with IEC/EN 60601-1-1. Anyone who connects additional equipment to the RS-232 serial connector configures a medical system, and is therefore responsible that the system complies with the requirements of IEC/EN 60601-1-1. If in doubt, call your local authorized service office, as listed on the back cover of this manual. The 3800 is referred to as an IEC/EN 60601/F device in the summary of situations table contained in IEC/EN 60601-1-1.

Cautions

Handle the monitor with care

Improper handling can cause damage or inaccurate results.

Cleaning

Do not autoclave, pressure sterilize, or gas sterilize the oximeter.

Use cleaning solution sparingly. Do not soak or immerse the monitor in liquid. Excessive solution can flow into the monitor and damage internal components.

When cleaning the display area, do not use abrasive cleaning compounds or other materials that could damage the screen.

Do not use petroleum-based solutions, acetone solutions, or other harsh solvents to clean the oximeter. These substances may damage the oximeter and cause a malfunction.

Battery

The 3800 internal battery, containing lead and acid, is a hazardous waste. Dispose of the battery through an approved hazardous materials disposal facility or return it to Datex-Ohmeda for disposal.

To prevent damage to the lead-acid battery, do not turn the monitor on after the LOW BATTERY message appears without first plugging it in to the AC power supply.

Sensors

Do not apply tension to the sensor cable; sensor damage may result.

Disposal

Dispose of this medical device and its packing materials according to local requirements.

Miscellaneous

US Federal law restricts this device to sale by or on the order of a licensed medical practitioner.

2/Setup and Operations

This chapter provides the following information and instructions:

- Powering the oximeter.
- Selecting the language, averaging mode, patient mode, PI_r pulsatile value display, and EMI (electromagnetic interference) line frequency.
- Checkout procedure—to determine that all functions of the oximeter are working properly.
- Signal and data validity guidelines.
- Trend data.

To operate the oximeter effectively, you must

- Know how the oximeter derives its readings (see *Principles of operation* in chapter 1).
- Be familiar with its controls and components (see chapter 1).
- Understand its messages (see chapter 3).

Powering the oximeter

The 3800 pulse oximeter is designed to operate on battery power and on all commonly available voltage supplies. Your oximeter was shipped with the correct power cord for your local AC power supply. Any hospital-grade power cord, however, with the female connector end that fits into the power module (IEC-320 type) on the 3800 can be used; the male connector that plugs into the grounded "wall" outlet may be whatever is needed locally. The oximeter accepts a range of AC mains power; see Appendix A for details.

To protect data validity in cases of possible electromagnetic interference, make sure the EMI line frequency mode switch is set to the same frequency as your local AC power supply before using the unit for patient monitoring; see *EMI line frequency* under *Mode switch settings* later in this chapter.

A battery does not need to be installed for the oximeter to operate on the AC power supply.

Setup

Factory settings and default settings

When you turn on the oximeter, the following settings are in effect and remain in operation until you change them.

Before powering on the oximeter

Use the mode switches in the oximeter's rear panel to set the language, averaging mode, patient mode, PI_r pulsatile value display, and EMI line frequency.

Parameter	Factory Setting	Range
Language	English	English, French, German, Italian, Japanese, Portuguese, Spanish, or Swedish
Averaging mode	Long / TruTrak+ (12 seconds)	Long / TruTrak+ (12 seconds), Medium (6 seconds) or Short (3 seconds)
Patient mode	Adult	Adult or Neonate
PI_r pulsatile value display	Yes	Yes (display PI_r value) or No
EMI line frequency	60 Hz	50 Hz or 60 Hz

After powering on the oximeter

Changes you make to the parameters shown below take effect immediately.

Parameter	Default Setting	Range
High SpO_2 limit	OFF (appears as: – – –)	50% to 100% or OFF
Low SpO_2 limit	85%	50% to 100% or OFF
High pulse rate	130 bpm* (adult mode) 200 bpm (neonatal mode)	30 to 235 bpm or OFF
Low pulse rate	40 bpm (adult mode) 100 bpm (neonatal mode)	30 to 235 bpm or OFF
Alarm volume	3	1 to 5
Pulse volume	2	1 to 5 or OFF

* bpm= beats-per-minute

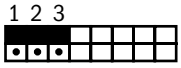
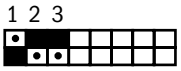
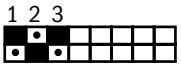
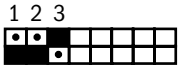
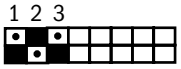
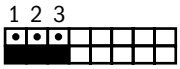
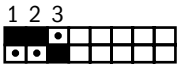
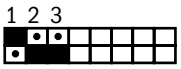
Mode switch settings

A bank of eight numbered, two-position switches is accessed through the rear panel. The up position is ON and the down position is OFF.

Important: If you change the switch settings while the oximeter is on, the new settings do not take effect until you power off, then on again.

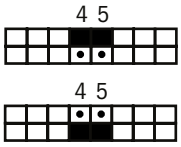
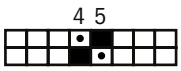
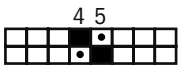
Language

Switches 1, 2, and 3 set the language used for the display and data transmitted through the RS-232 port. (For Japanese, data transmissions are in English only.)

Switches	Language
	English
	French
	German
	Italian
	Japanese
	Portuguese
	Spanish
	Swedish

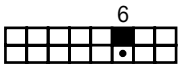
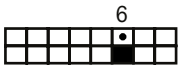
Averaging mode

Switches 4 and 5 set the averaging mode. The averaging mode selects the time period of data used to calculate a weighted average SpO_2 value to be displayed by the oximeter.

Switches	SpO_2 and Pulse Rate Averaging	TruTrak+
	Long (12 seconds)	Yes (enabled)
	Medium (6 seconds)	No
	Short (3 seconds)	No

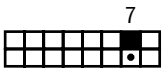
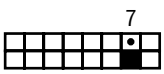
Patient mode

Switch 6 sets the patient mode.

Switch	Patient mode	Low pulse rate alarm limit	High pulse rate alarm limit
	Adult	40 bpm	130 bpm
	Neonate	100 bpm	200 bpm

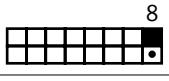
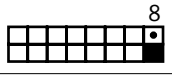
PI_r pulsatile value display

Switch 7 sets the display of the PI_r pulsatile value.

Switch	Display PI_r value
	Yes
	No

EMI line frequency

Switch 8 sets the EMI line frequency. To optimize EMI (electromagnetic interference) immunity, make sure switch 8 is in the correct position for the AC power line frequency in use.

Switch	EMI Line Frequency
	60 Hz
	50 Hz

Checkout procedure

WARNING: Failure of operation. If the oximeter fails any part of the checkout procedures or current leakage tests, remove it from operation until qualified service personnel have corrected the situation.

WARNING: Explosion hazard. Do not use the monitor in the presence of any flammable anesthetic mixture.

WARNING: Electrical shock hazard. This equipment must be properly grounded.

- **Electrical safety specifications (e.g., current leakage and ground resistance) can be assured only when the monitor is connected to a three-wire, grounded receptacle without the use of extension cords or adapters.**
- **If there is any doubt about the integrity of the AC power supply protective earth conductor, operate the monitor on internal battery power.**
- **Because the unit is not grounded when it is operating on battery power, do not connect any equipment to the RS-232 connector on the rear panel unless the unit is connected to the AC power supply.**

If you plan to send serial data to another device, make sure the connection between the device and the rear panel connector is made **before** you power on the monitor **and make sure the monitor is connected to the AC power supply.**

Important: For TruTrak+ performance, the averaging mode must be set to Long.

1. Inspect the oximeter case for damage. Make sure the display windows are clean.

   WARNING: Sensors

   - **Discard a damaged sensor immediately. Do not repair a damaged sensor or use a sensor repaired by others.**
   - **To prevent patient injury or equipment damage, use only Datex-Ohmeda oximeter sensors approved for use with this oximeter. For complete information about the safe and appropriate use of a sensor, consult the instructions for that sensor.**

   CAUTION: Do **not** apply tension to the sensor cable; sensor damage may result.

2. Check that the sensor is a compatible model before connecting it to the oximeter. Only Datex-Ohmeda OxyTip+ sensors can be used with this monitor.

   If you're using a reusable sensor, make sure it opens and closes smoothly. Remove substances that may interfere with the transmission of light between the sensor's light source and detector.

3. Connect the sensor cable to the sensor connector on the monitor. Make sure it is a firm connection and that the cable is not twisted, sliced, or frayed.

4. Attach the sensor to a finger or an ear, depending on the sensor you are using.

5. To turn on the oximeter, press the power button.

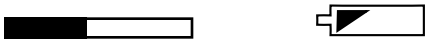
   The first screen shows the Datex-Ohmeda logo and the model name (Model 3800).

   The next screen shows the averaging mode in effect, the patient mode, the progress of the self-test, and the status of the battery charge.

   Averaging Mode: **Long**

   Patient Mode: **Adult**

   Self-test in progress ...

   (indicates battery-charge status)

   Below the bar graph, the version number of the unit's system and oximetry software appears as Version X.XXX/YY.YYY, where X's represent the system software version and Y's the oximetry software version.

   Diagnostic self-test

   During this time, the system performs a diagnostic self-test (electronics, battery status, analog signal path integrity, calibration check) and sets the default parameters. This self-test takes approximately 10 seconds.

   - A start-up tone sequence tests the audio circuit; all display LEDs and the LCD backlight are illuminated, then blanked.
   - The alarm LED toggles between red and yellow while a numeric countdown from 9 to 0 occurs on each seven-segment LED display ending with a decimal point.
   - A battery icon is displayed to indicate the battery condition as either charged, depleted, or defective/missing (see chapter 3).

   Upon successful completion of all diagnostic self-tests, the unit is considered to be in calibration and begins normal operation. This message is displayed:

   Test passed. In calibration.

   If the unit does not pass the self-test, an error message is displayed and the unit is inoperable.

6. On the displays, verify
   - The high and low alarm limits for SpO_2 and pulse rate.
   - Dashes (– – –) appear for any limit set to OFF.
   - The readings for SpO_2, pulse rate, and PI_r pulsatile value.

     Dashes may appear on the display until the SpO_2, pulse rate, and PI_r pulsatile value readings have stabilized (approximately 12 seconds).

NOTE: The audible alarm feature for all alarm conditions is silenced for the first two minutes after powering on.

7. If two minutes have elapsed since you powered on, verify that the patient alarms are functional by setting the high and low SpO_2 and pulse rate alarm limits beyond the current readings. Make sure
   - An alarm tone sounds.
   - The violated alarm limit and reading flash on the display.
   - Depending on the priority of the alarm, a red or yellow alarm light flashes.
8. Verify the sensor alarms are functional by removing the sensor from the sensor site. Make sure
   - SENSOR OFF or CHECK SENSOR SITE appears in the message area of the graphic display.
   - The alarm tone sounds; the alarm light flashes.
9. Unplug the sensor from the oximeter. Make sure
   - NO SENSOR appears.
   - The alarm tone sounds; the alarm light flashes.
10. Press the alarm silence button. Make sure
    - The alarm tone ceases.
    - The alarm light is steady.
11. To begin patient monitoring, connect the desired Datex-Ohmeda sensor to the oximeter. Attach that sensor to the patient.

To verify the sensor is on correctly and that the data are verifiable, see *Signal and data validity* in this chapter.

WARNING: Patient safety. Patient conditions (such as reddening, blistering, skin discoloration, ischemic skin necrosis, and skin erosion) may warrant changing the sensor site frequently or using a different style of sensor.

Signal and data validity

Plethysmographic waveform

The oximeter's PerfTrak waveform display provides a visual indicator of the validity of the values that appear on the display. The waveform is scaled to correspond to the perfusion level or strength of the signal being received at the patient monitoring site.

NOTE: When a message appears in the upper portion of the LCD, the waveform rectangle becomes smaller but the correspondence between signal strength and waveform height is maintained.

You should be able to easily identify three complete passes of the plethysmographic waveform. Although the waveform shape may vary from patient to patient, under normal conditions it corresponds to the arterial pressure waveform. Use Figures 2-1 (adult) and 2-2 (neonate) as guidelines to determine a sensor placement that generates the fewest noise spikes.

Figure 2-1. Typical adult plethysmographic waveform

Figure 2-2. Typical neonate plethysmographic waveform

The "typical" neonate waveform differs from that of an adult, including the absence of a dicrotic notch (a notch on the descending limb of the normal arterial pulse tracing that corresponds to aortic valve closure).

Low perfusion

As the perfusion at the patient monitoring site decreases, so will the height of the waveform. (The PI_r pulsatile value is a numeric representation of the relative height of the waveform.) The height will decrease to the point where the signal quality becomes too small or too poor for accurate, reliable readings. At that point, the message CHECK SENSOR SITE appears in the message area and an alarm is generated. The waveform will be similar to Figure 2-3.

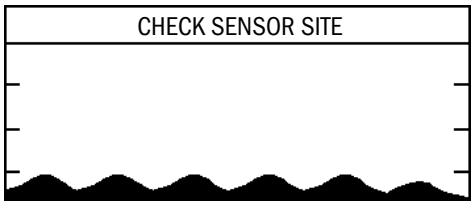


Figure 2-3. Low perfusion waveform

Signal noise

The following conditions can cause noisy waveforms:

- Poor sensor placement.
- Motion at the sensor site.
- Electrical interference.

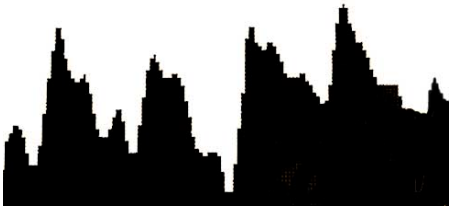


Figure 2-4. Noisy plethysmographic waveform

If three easily identifiable passes of a “typical” waveform do not occur,

- Make sure the sensor’s detector is flush with the sensor site (for sensor application, see the instructions for the sensor you are using).
- Make sure the light source and detector are directly opposite each other.
- Select a site where the distance between the light source and the detector is less.
- Make sure the patient site is stable; minimize movement of the sensor site.
- Massage the sensor site with a 70% isopropyl alcohol pad or rubefacient cream (10-30% methyl salicylate and 2-10% menthol) for 20-30 seconds. Strong vasodilator creams, such as nitroglycerin paste, are not recommended.
- If possible, remove electrical noise sources such as electrosurgery or electrical/electronic devices (e.g., fans). If these solutions are not possible, operate the oximeter on battery power, or try plugging the oximeter into a different electrical outlet.
- If artificial nails or excessive fingernail polish are present, select another site or remove the polish/artificial nails.

Numeric display

SpO_2

Stability of the SpO_2 readings is a good indicator of signal validity. Although “stability” is a relative term, with practice you’ll get a good feeling for changes that are artifactual or physiological and the speed of each. The stability of the readings over time is affected by which averaging mode you're using. In Long / TruTrak+ mode (12-second averaging), the readings tend to be more stable because the signal is averaged over a longer period of time than the Short (3 seconds) or Medium (6 seconds) modes.

Too great a distance between the sensor emitter and detector can reduce signal strength and result in a poor signal. When the value is too low, the message CHECK SENSOR SITE may appear to alert you that the SpO_2 value may not be accurate. Perfuse the sensor site or relocate the sensor to a site with higher blood flow.

Pulse rate

Compare the displayed pulse rate to the patient's palpated pulse rate. If the unit's rate varies significantly from the palpated rate, the data may be less accurate due to motion artifact or other noise.

A cough or other hemodynamic pressure disturbance can disrupt the pulse rate, which is determined from the plethysmographic waveform. The time span between the waveform's peaks determines the pulse rate. The unit uses the same averaging mode (long, medium, or short) as that selected for SpO_2.

PI_r pulsatile value

The PI_r pulsatile value is a measurement of the strength of the photoplethysmographic signal read by the oximeter. The greater the number, the greater the pulsatility and the validity of the SpO_2 and pulse rate data. This value is useful when determining that the sensor is correctly attached and that the data are verifiable. It is also an indicator of relative perfusion at the sensor site.

Trend data

The oximeter stores a maximum of 12 hours of trend data. The process maintains the lowest SpO_2 value that occurs during each 6-second interval along with the corresponding pulse rate, and highest-priority error message and all alarm limit violations. You can access the trend data stored in the 3800 through the serial port on the rear of the oximeter. See Appendix B for details.

The trend data are maintained as long as the unit's battery is connected and charged to minimum operating level.

To clear trend data:

1. Hold down the alarm silence button while you power on the oximeter.
2. At the Clear Trend Data? prompt,
   - To select YES to clear all data from the trend buffer, press the high SpO_2 button (+ or –).
   - To select NO to retain the data, press the low pulse rate limit button (+ or –).

If you don't press either button within 10 seconds, the trend data are retained and the unit proceeds with the power-on sequence.

3/Messages and Troubleshooting

This chapter contains

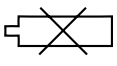
- Descriptions of the messages and indicators that appear on the screen.
- Alarm categories and their characteristics.
- A chart for troubleshooting situations that may occur while using the oximeter.

Become thoroughly familiar with this information before using the oximeter to monitor a patient.

Messages

The pulse oximeter acknowledges your actions and the monitor's conditions by displaying messages in the waveform screen message display area. Alarm messages appear when any alarm condition occurs.

The following chart alphabetically lists the messages that may appear on the oximeter, why the message appears, and the action(s) to take if the message indicates a problem.

Message	Possible cause(s)	Recommended action(s)
 Appears between the alarm limit settings.	The all mute feature is activated.	No action required. (Press the alarm silence button once to deactivate.)
	Indicates a fully charged battery.	No action required.
 Appear on status screen during power-on sequence and on right side of LCD during battery operation.	Indicates a low-charged battery.	To recharge, plug the unit into AC mains power.
 Appears on status screen during power-on sequence.	Indicates battery failure, or a depleted or missing battery.	To recharge, plug the unit into AC mains power. If the condition persists, the unit requires service.
 Appears in message area on waveform screen.	The alarm or pulse tone volume is being adjusted.	No action required. To adjust audio volume, see *Front panel* in chapter 1.

Message	Possible cause(s)	Recommended action(s)
AMBIENT LIGHT	Excessive ambient light.	Relocate the sensor to a site more shielded from light or reduce the amount of light shining on the sensor.
BUTTON STUCK	Appears if something is pressing against the buttons on the monitor.	Make sure nothing is pressing against the front of the unit.
	Appears when the last button you pressed has not released properly or has been pressed for more than 30 seconds.	Press that button again or turn the power off and then on. If the condition persists, the unit requires service.
CHECK SENSOR SITE	Appears when SpO_2 readings may be invalid due to motion, an unacceptable sensor site, poor placement, low perfusion, or because the sensor is off the patient.	For all causes, reposition or relocate the sensor, and/or increase perfusion (see the sensor user instructions).
Clear Trend Data? **YES/NO**	Appears when the alarm silence button is held down while you're turning on the oximeter.	Press the high SpO_2 alarm limit button (+ or –) to clear trend data from memory (YES). Press the low pulse rate alarm limit button (+ or –) to retain trend data in memory (NO). If you take no action within 10 seconds, the trend data are retained in memory.
CONNECT UNIT TO LINE POWER	The battery needs immediate recharging.	Plug the oximeter into the AC power supply; otherwise the unit will turn itself off in 10 seconds.
INSUFFICIENT LIGHT	Dirt on the sensor emitter or detector. Sensor detector failure.	Clean the sensor (if reusable) or replace it.
	Test site dirty. Misaligned or poorly positioned sensor.	Clean the test site. Reposition the sensor or select another test site.
	Insufficient light penetrating the tissue site. Dark pigmentation.	Reposition the sensor or select another test site.
	Fingernail polish present.	Remove polish or select another test site.

Message	Possible cause(s)	Recommended action(s)
INTERFERENCE DETECTED	Appears when the signal Is too erratic to be processed due to proximity of other electrical equipment generating high-frequency electromagnetic noise.	No action required. May be caused by strong radio frequency (RF) interference possibly generated by electrosurgery. SpO_2 and PR readings do not change during detected interference (or become dashes if interference persists). When interference ceases, signal processing resumes.
LOW BATTERY	Appears when 5 to 15 minutes of battery operation remain.	Plug the oximeter into the AC power supply to recharge the battery and continue monitoring. **Important**: To prevent permanent damage to the battery, recharge a discharged battery within eight hours after the LOW BATTERY message is displayed.
LOW QUALITY SIGNAL (appears only in serial communication output)	Sensor off patient.	Reattach the sensor.
	Perfusion not sufficient for valid readings. Motion at sensor site, electrical noise, or incorrect sensor placement.	Check patient and oximeter setup.
NO SENSOR (also see **CHECK SENSOR SITE**)	Sensor not connected or not fully inserted into the sensor connector.	Insert sensor cable into the connector.
	May be an incorrect sensor.	Refer to the instructions for the sensor you are using.
SENSOR FAILURE	The connected sensor is not an OxyTip+ sensor.	Connect a Datex-Ohmeda OxyTip+ sensor.
	Oximeter can't identify the connected sensor.	Replace sensor. Refer to the instructions for the sensor you are using.
	Broken sensor cable wire, inoperative LEDs, or faulty detector; the sensor has failed.	Replace sensor.
SENSOR OFF	Sensor off patient.	Reattach the sensor.
SYSTEM FAILURE #XXX: SERVICE UNIT	An internal component of the unit has failed. XXX represents the error code.	Unit requires service.
TruTrak+ OFF	TruTrak+ technology is not active; the averaging mode is not set to Long.	For TruTrak+ performance, set the averaging mode to Long (see *Setup* in chapter 2).

Alarm categories

3800 oximeter tiered alarms fall into three priority categories: high, medium and low. Depending on what is occurring at the time, an alarm may fall into more than one category.

NOTE: The audible alarm feature for all alarm conditions is silenced for the first two minutes after powering on.

High priority

Requires immediate operator response.
Red alarm button light flashes.
Two five-tone sequences (beep-beep-beep, beep-beep) sound every 10 seconds until the condition is removed or the alarm is silenced

- A violation of the low or high SpO_2 limit (violated limit flashes).
- BUTTON STUCK
- CONNECT UNIT TO LINE POWER

If the following alarms occur during active monitoring, they also fall into the high priority category.

- AMBIENT LIGHT
- CHECK SENSOR SITE
- INSUFFICIENT LIGHT
- NO SENSOR
- SENSOR FAILURE
- SENSOR OFF

NO SENSOR and SENSOR OFF alarm conditions are not active until after the oximeter displays an initial valid reading.

Medium priority

Requires prompt operator response.
Yellow alarm button light flashes.
One three-tone sequence (beep-beep-beep) every 20 seconds until the condition is removed or the alarm is silenced.

- A violation of the low or high pulse rate limit (violated limit flashes).
- INTERFERENCE DETECTED
- LOW BATTERY

If the following alarms occur **before** active monitoring, these alarms are considered to be of medium priority:

- AMBIENT LIGHT
- CHECK SENSOR SITE
- INSUFFICIENT LIGHT
- NO SENSOR
- SENSOR FAILURE
- SENSOR OFF

Low priority

Requires operator awareness.
Yellow alarm button light illuminates continuously.
One tone (beep) sounds; no repetition.

- INTERFERENCE DETECTED

Requires operator awareness.
Yellow alarm button light illuminates continuously.

- LOW QUALITY SIGNAL

System failure

A special category of alarms exists for system failure and the imminent failure of pulse oximeter operation.

Requires immediate operator response.
Red alarm button light continuously flashes.
A continuous tone sounds; overrides all mute condition.

- SYSTEM FAILURE #XXX, SERVICE UNIT

For more information, refer to the *3800/3900/3900P Technical Reference Manual.*

Troubleshooting

The following chart list some conditions that may occur with the oximeter along with the cause(s) and recommended action(s) for correcting them.

Condition	Possible cause(s)	Recommended action(s)
Unit does not power on.	The battery is fully discharged or disconnected and/or the unit is not plugged into the AC power supply.	To charge the battery and begin monitoring, plug the unit into the AC power supply. If the condition persists, the unit requires service.
	One or both of the fuses have blown.	Replace the fuse(s). See *Replacing the fuses* in chapter 4. If the new fuse blows shortly after installation, the unit requires service.
Unit powers on but the graphic display is blank.	The viewing contrast is not correct.	Use the display contrast adjust slide to adjust the viewing angle. If the condition persists, the unit requires service.
Continuous speaker tone.	Internal failure.	Unit requires service.
Buttons don't work when pressed.	Internal failure.	Unit requires service.
Unit doesn't beep when powered on.	Disconnected or failed speaker.	Unit requires service.
Dashed display, waveform may appear erratic; various alarm messages	Sensor failure.	Replace sensor. See CHECK SENSOR SITE under *Messages* in this chapter.

4/Maintenance and Service

This chapter covers

- Maintenance procedures:

  Cleaning the oximeter, as necessary.

  Recharging the battery, as necessary.

  Replacing the fuses in the power module, as necessary.
- The Datex-Ohmeda repair policy.
- A list of items you may order for the oximeter.

Cleaning

To clean a reusable sensor, refer to the instructions for the sensor.

Oximeter

WARNING: Electrical shock and flammability hazard. Before cleaning the oximeter, always turn it off and disconnect the power cord from the AC power supply.

CAUTION:

- Do not autoclave, pressure sterilize, or gas sterilize this oximeter.
- Use cleaning solution sparingly. Do not soak or immerse the monitor in liquid. Excessive solution can flow into the monitor and damage internal components.
- When cleaning the display area, do not use abrasive cleaning compounds or other materials that could damage the screen.
- Do not use petroleum-based solutions, acetone solutions, or other harsh solvents to clean the oximeter. These substances may damage the oximeter and cause a malfunction.

Be sure that the oximeter is turned off and unplugged from the AC power supply before cleaning and that the unit is completely dry before use.

To clean the display panel, use a cotton swab moistened with 70% isopropyl alcohol and gently wipe the panel.

To clean the outer surface of the oximeter, use a soft cloth dampened with a mild soap and water solution or one of the following solutions:

70 vol% isopropyl or ethyl alcohol

quaternary ammonia

3 vol% hydrogen peroxide in water

100:1 bleach solution

Cidex® plus activator (ready solution contains 2 vol% glutaraldehyde)

Recharging the battery

The oximeter's internal battery (a sealed pack of 8V lead-acid batteries) provides the following operation times when it is new, used at normal temperatures, and charged to full capacity: at least 5 -1/2 hours of continuous operation.

A LOW BATTERY message appears when 5 to 15 minutes of battery operation remain. When the alarm message CONNECT UNIT TO LINE POWER appears during operation on battery power, an audible alarm sounds and the oximeter automatically shuts off in approximately 10 seconds.

Important: To prevent permanent damage to the battery, recharge a discharged battery within eight hours after the LOW BATTERY message is displayed.

To recharge the battery, plug the oximeter into the AC power supply. The oximeter is operational while recharging the battery.

The battery charging times are approximately

- 4 hours for 80% battery capacity.
- 8 hours for 100% battery capacity.

Under normal conditions, the battery lasts for several hundred charge/discharge cycles. The battery will not overcharge.

Batteries stored for extended periods of time should be recharged every six months to maintain the charging capacity of the battery.

Replacing the battery

If the battery will no longer recharge with AC power connected, it should be replaced. Battery replacement should be performed by authorized service personnel only.

Replacing the fuses

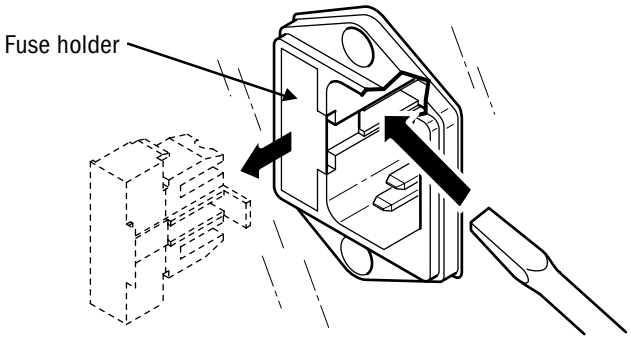
Should a power problem blow one or both of the fuses in the power input module on the rear panel, you'll need to replace them.

Tool required

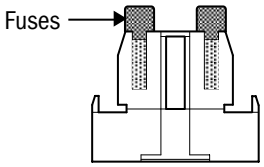
Small flat-blade screwdriver, 5 mm (3/16 inch)

WARNING: To protect against fire hazard, replace only with fuses of the same type and voltage rating.

1. Power off the oximeter and unplug the power cord from the back of the oximeter.
2. Insert the small flat-blade screwdriver into the center slot of the fuse holder. Gently pry loose and remove the fuse holder.



3. Note how the fuses are placed in the fuse holder for installation of the new fuses.



4. To remove the fuses from the fuse holder, use the edge of the screwdriver blade to pry against the bottom of the metal portion of the fuse where it is secured to the glass portion of the fuse.
5. Place the new fuse(s) (T2.0AH/250V) in the fuse holder, properly orienting them as shown above.
6. Slide the fuse holder back into the power entry module and press firmly to make sure it is fully inserted.

NOTE: If the fuses blow shortly after replacement, the unit requires service.

Repair policy and procedure

Contact Datex-Ohmeda or your authorized service office (see the back cover of this manual) to order parts or for assistance.

Do **not** use malfunctioning equipment. Have the unit repaired by Datex-Ohmeda. After repair, perform the *Checkout procedure* (in chapter 2) to verify the unit is fully functional.

WARNING: Do not remove the cover of the monitor. An operator may only perform maintenance procedures specifically described in this manual. Refer servicing to qualified service personnel trained in the repair of this equipment.

Packaging and return procedure

If you are instructed to ship the monitor to Datex-Ohmeda or to an authorized service office for repair, follow these steps:

1. Clean the monitor. Make sure it is completely dry before you pack it for shipment.
2. Package the monitor carefully for shipment (in the original shipping container if possible).
3. You may be required to enclose the following items (when you call for assistance, verify the shipping requirements):
   - A letter describing the problem in detail.
   - Person (name, telephone/fax number, and country) to contact for questions about necessary repairs.
   - Ship-to and bill-to information.
   - Purchase order number for tracking purposes or to cover repairs if the oximeter is not under warranty.
4. Ship the monitor as directed by your service office.

Parts list

Description		REF
Sensors Refer to the sensor chart that accompanies this manual for a list of the sensors you can use with the 3800. Only Datex-Ohmeda OxyTip+ sensors can be used with this monitor.		
Battery pack		6050-0004-277
Carrying case, 3800		6050-0004-610
3800 User's Manual		
	Danish	6050-0006-382
	English	6050-0006-380
	Finnish	6050-0006-384
	French	6050-0006-386
	German	6050-0006-388
	Italian	6050-0006-390
	Japanese	6050-0006-392
	Polish	6050-0006-394
	Portuguese	6050-0006-396
	Spanish	6050-0006-398
	Swedish	6050-0006-400
3800/3900/3900P Technical Reference Manual, English		6050-0006-404
Service kit, PCA drawings		6050-0006-476
Power cord		
Socket Type:	*Commonly Used In:*	
	Australia, China	6030-0000-001
	Canada, Japan, Latin America, USA	0208-0943-300
	Continental Europe	6030-0000-006
	Italy	6030-0000-002
	United Kingdom	6050-0002-259

A/Compliance and Specifications

This chapter contains

- Information about the tests that were conducted and the regulations with which the oximeter complies to assure its safe use.
- Performance specifications for the oximeter.

Compliance with standards

The presence on the monitor of any symbol described below indicates compliance with the standard represented by that symbol.

CE 0197 Medical Device Directive 93/42/EEC of the European Union for a class I (with a measuring function), IIa, IIb, or III device.

LR 87853 C SP US Medical electrical equipment classified in the US and Canada with respect to electric shock, fire, and mechanical hazards only, in accordance with the Canadian Standards Association CAN/CSA C22.2 No. 601.1 and Underwriters Laboratories Inc. UL 2601-1.

General safety requirements

The 3800 complies with the requirements of IEC/EN 60601-1 Part 1: General requirements for safety of medical electrical equipment.

 Type BF applied part.

Type of protection against electric shock: Class I/Internal electrical power source

Degree of protection against ingress of liquids: Ordinary (IPX0)

Mode of operation: Continuous

The monitor also complies with the following:

EN 865 Pulse oximeters – Particular requirements

EN 475 Medical devices – Electrically-generated alarm signals

Electromagnetic compatibility (EMC)

The 3800 complies with the requirements of IEC/EN 60601-1-2: Electromagnetic compatibility – Requirements and tests.

Emissions IEC/EN 55011 Group I, Class B

The 3800 pulse oximeter was tested with an RS-232 cable attached when operating on AC power. It was tested with no peripheral devices when operating on battery power.

When installing and using this monitor, take precautions to ensure electromagnetic compatibility. For more information, refer to the *3800/3900/3900P Technical Reference Manual*.

Electromagnetic effects

Electromagnetic interference, including interference from portable and mobile radio frequency (RF) communications equipment, can affect this monitor. Indications that the 3800 is experiencing electromagnetic interference include the following:

- Variations in the PerfTrak waveform display.
- Sudden increases or decreases in the waveform height that do not correlate to the physiological condition of the patient.
- Sensor-related messages that are not resolved by the instructions found in this manual.
- The display of dashes on numeric LEDs when a valid physiological signal is present.

This interference may be intermittent and careful correlation between the effect and its possible source is important. Indications of interference should not occur if the monitor is used within its intended electromagnetic environment.

Safety checks for software

The Datex-Ohmeda software design controls include performance of a risk analysis using methods consistent with EN 1441 Medical devices – Risk analysis.

To ensure proper operation of the software, the 3800 employs three separate watchdog circuits for the microprocessors, power-on self-tests (including memory checksum and calibration verification), and memory tests during monitoring. The software continuously monitors the patient sensor and, if a failure is detected, discontinues power to the sensor.

Specifications

Unless otherwise indicated, all specifications are nominal and are subject to change without notice.

Circuitry

Microprocessor-controlled

Automatic self-test of oximeter when powered on

Automatic setting of default parameters

Automatic alarm messages

Trend data output of SpO_2, pulse rate, and alarm messages via RS-232 serial port—up to 12 hours of stored data

Audio indicators

Adjustable-volume audible pulse

Adjustable-volume audible alarm tone

Pitch modulation reflects changing SpO_2 levels

Alarm silence (120 seconds); all mute (continuous silence)

Pulse rate out-of-limits alarm

SpO_2 level out-of-limits alarm

Sensor-condition alarms

System-failure and recharge-battery alarms

Audible alarms

Setting levels available:

Alarm: 1 through 5

Pulse beep: OFF and 1 through 5

Intensity at 1-meter distance:

Volume setting of 1: 55 decibels (minimum)

Volume setting of 5: 85 decibels (maximum)

Alarm limits

SpO_2 alarm limit range:

High = 50 to 100% or OFF

Low = OFF or 50 to 100%

Pulse rate alarm limit range in beats per minute (BPM):

High = 30 to 235 or OFF

Low = OFF or 30 to 235

Displays

The displayed SpO_2, pulse rate, and PI_r values are updated every second. The plethysmographic waveform sweep is updated every 4 seconds.

Numeric display (Light-Emitting Diodes–LEDs)

Arterial oxygen saturation (SpO_2) reading

Pulse-rate reading

Graphic display (Liquid Crystal Display–LCD)

Plethysmographic waveform

PI_r pulsatile value

High and low SpO_2 alarm limits settings

High and low pulse rate alarm limits settings

Sensor condition alarms

System operational status messages

Alarm messages

Contrast adjustment for best viewing

Mode switch

Language: English (factory setting), French, German, Italian, Japanese, Portuguese, Spanish, or Swedish

Averaging mode: Long / TruTrak+ (12 seconds–factory setting), Medium (6 seconds), or Short (3 seconds)

Patient mode: Adult (factory setting) or Neonate

PI_r pulsatile value display: Yes (factory setting) or No

EMI line frequency: 60 Hz (factory setting) or 50 Hz

SpO_2

Range: 0 to 100%

Accuracy, A_{rms} (previously represented by 1 Standard Deviation):
70 to 100% ± 2 digits
70 to 100% ± 3 digits during conditions of clinical patient motion (with TruTrak+ enabled)
Below 70% unspecified

Resolution: 1%

Interfering substances

Carboxyhemoglobin may erroneously increase readings. The level of increase is approximately equal to the amount of carboxyhemoglobin present. Dyes, or any substances containing dyes, that change usual arterial pigmentation may cause erroneous readings.

Pulse rate

Range: 30 to 250 bpm

Accuracy assuming a constant pulse rate: ± 2% or ± 2 bpm (whichever is greater)

Accuracy during conditions of clinical patient motion: unspecified

Resolution: 1 bpm

PI_r pulsatile value

Range: 0.00 to 9.99

Averaging interval: 12 seconds

Resolution: 0.01

Sensor emitter wavelength ranges

Red LED peak wavelength range: 650 to 665 nm

Infrared (IR) LED peak wavelength range: 930 to 950 nm

Average power: ≤ 1 mW

Environmental

Parameter	Operating	Transport and Storage
Temperature	0 to 50 °C (32 to 122 °F)	–40 to 70 °C (–40 to 158 °F)
Relative humidity	5% to 95% noncondensing	5% to 95% condensing
Pressure	106 to 47 kPa	106 to 47 kPa
Approximate elevation	–378 to 6000 m (–1240 to 19,686 ft.)	–378 m to 6000 m (–1240 to 19,686 ft.)

Electrical

Battery

Type: pack of 8-volt, sealed lead-acid

Capacity: 3.2 ampere hours

Operation time for a new battery at normal operating temperatures: at least 5 1/2 hours (with all functions operative from a fully charged battery)

Low battery indicator (LOW BATTERY): when the battery has between 5 and 15 minutes remaining capacity

Charge time:
4 hours = 80% capacity
8 hours = 100% capacity

Life: several hundred charge/discharge cycles

Power

Consumption (typical): 15 watts

Input voltage range: 90 to 264 VAC at 47-63 Hz

Current (typical): 0.45 A(rms) at 100 V, 0.37 A(rms) at 120 V, 0.25 A(rms) at 220/ 230/240 V

Current leakage

With power on, forward or reverse polarity: 100 microamperes maximum

Ground resistance: less than 0.1 Ω

Fuses

T2.0AH/250V, 5 mm (OD) x 20 mm (length)

Serial output, RS-232

Data output every 2 seconds (auto-output mode) or 6 seconds (trend-output mode): SpO_2, pulse rate, alarm limit violation messages, and displayed alarm/error messages.

9600 baud

Full duplex

Number of bits per character: 8

Parity: none

Bits: 1 start, 1 stop

Handshaking: CTS/RTS

Connector type: 9-pin standard D, female

Connector pin functions:

2 = oximeter receives data
3 = oximeter transmits data
5 = signal ground
7 = RTS
8 = CTS

Dimensions and weight

Height: 9.4 cm (3.7 in.)

Width: 24.4 cm (9.5 in.)

Height: 22.5 cm (8.9 in.)

Weight: 2.9 kg (6.5 lb.)

B/Communications

This appendix covers serial device connections for computer/oximeter communication.

WARNINGS: Electrical shock hazard

- **Measure the oximeter's leakage current whenever an external device is connected to the RS-232. Forward and reverse polarity: 100 microamperes maximum.**
- **Because the unit is not grounded when it is operating on battery power, do not connect any equipment to the RS-232 connector on the rear panel unless the unit is connected to the AC main power supply.**

WARNING: RS-232 system interconnection. Accessory equipment connected to the RS-232 connector must be certified according to the current version of the respective IEC/EN standards (e.g., IEC 60950 for data processing equipment and IEC/EN 60601-1 for medical equipment). All configurations shall also comply with IEC/EN 60601-1-1. Anyone who connects additional equipment to the RS-232 connector configures a medical system, and is therefore responsible that the system complies with the requirements of IEC/EN 60601-1-1. If in doubt, call your local authorized service office, as listed on the back cover of this manual. The 3800 is referred to as an IEC/EN 60601/F device in the summary of situations table contained in IEC/EN 60601-1-1.

Serial device communications

Requirements

Connect the oximeter only to computers with

- An RS-232 interface.
- The ability to accept ASCII-formatted data at a baud rate of 9600.

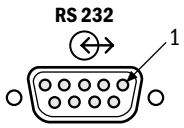
The settings on the computer must be:

9600 baud
8-bit data
No parity
1 stop bit
1 start bit
Full duplex
Handshaking, CTS/RTS

RS-232 interface cable—serial pinout

Important: Use only a cable designed to interface directly between your computer's connector and the RS-232 connector on the oximeter.

Configure the RS-232 interface cable as follows:



Pin 2 Oximeter receives data
Pin 3 Oximeter transmits data
Pin 5 Signal ground
Pin 7 RTS
Pin 8 CTS

Pins 1, 4, 6, and 9 are not used.

Connection

To acquire trend data on the computer, the computer must be running a third-party communications program, such as ProComm™ or Microsoft Windows Terminal™, set to receive at 9600 baud.

Equipment needed

- A board for the computer that supports serial communication with the same serial port connections as the oximeter.
- A male (DB-9P) to female (DB-9P) interface cable with the proper pin connections.
- A third-party communication program.

Procedure

1. Locate the serial connector on the rear panel of the oximeter and connect the male end of the RS-232 interface cable to it.
2. Locate the RS-232 interface connector on the rear panel of the computer and connect the female end of the RS-232 interface cable to it.
3. Make sure that the RS-232 interface cable is securely connected on both ends.
4. Make sure the computer's communication program is running and ready to receive data at the correct baud rate.

Serial communication output

The oximeter is capable of two-way communication with computers:

- Auto-output mode (default)—current data.
- Trend-output mode—trend data stored in the oximeter's memory.

To use these modes,

- The oximeter must be connected to the computer.
- The computer must be running a communications program.

SpO_2, pulse rate, and alarm conditions are transmitted and updated every two seconds in auto-output mode or every six seconds in trend-output mode. One line of ASCII data is output to the computer every two seconds in auto-output mode, or every six seconds in trend-output mode.

The information sent to the computer screen is formatted similarly to the following example:

```
Model 3800 Pulse Oximeter
TREND DATA OUTPUT
6 SECONDS PER DATA POINT
:       1   ** POWER ON **
:       2   SpO2= ---    PR=   ---
:       3   SpO2= ---    PR=   ---    SENSOR OFF
:       4   SpO2= 95     PR=    0    LOW PR
:       5   SpO2= 95     PR=    0    LOW PR
:       6   SpO2= 95     PR=   93
:       7   SpO2= 95     PR=   92
:       8   SpO2= 94     PR=   96    HIGH PR
:       9   SpO2= 89     PR=   96    LOW SPO2, HIGH PR, BUTTON STUCK
:      10   SpO2= 92     PR=  100    HIGH PR, BUTTON STUCK
:      11   SpO2= 95     PR=   99
:      12   SpO2= 95     PR=   98
:      13   SpO2= ---    PR=   ---    NO SENSOR
:
::
END TREND DATA
```

Auto-output mode

This is the default mode, which transmits monitoring data being currently collected. It is present when the oximeter begins communication with a computer, and is the mode the oximeter returns to when exiting from other modes.

Messages relating to SpO_2, pulse rate, and alarm limits violations that appear on the oximeter also appear on the computer.

Trend-output mode

This mode allows up to 12 hours of trend data to be output to a computer.

NOTE: 12 hours of trend data are output in approximately 5 minutes.

To enter trend-output mode:

Enter: <esc> CJ <enter>

While trend data are being output, messages that appear on the oximeter do **not** appear on the computer but they are stored in trend.

To exit trend-output mode while trend data are being output:

Enter: <esc> CK <enter>

After trend data are output, auto-output mode automatically resumes. Trend data are still in memory and can be output again without turning the oximeter off and on again.

NOTE: No other modes can be activated through the computer interface while in trend-output mode; only the trend output exit command is recognized.

To clear-trend data in the oximeter's memory using the computer:

Enter: <esc> CP <enter>

Warranty

The 3800 Pulse Oximeter (the product) is sold by Datex-Ohmeda, Inc. only under the warranties set forth in the following paragraphs. Such warranties are extended only with respect to the purchase of the product directly from Datex-Ohmeda Authorized Dealers as new merchandise and are extended to the first Buyer thereof, other than for resale.

Limited warranty

Datex-Ohmeda warrants that the product meets the published specifications at the time of shipment from the factory.

Products not under warranty

The following items are not covered under this warranty: disposable items, accessories, service kits, and replacement parts. These items may be covered under a separate warranty. Consult Datex-Ohmeda for details.

Duration

The product is warranted against defects in materials and workmanship for a period of three (3) years from the date of delivery to the user (in no event for a period of more than four [4] years from the date of original delivery by Datex-Ohmeda to an Authorized Dealer). The battery is warranted against defects in materials and workmanship for one (1) year from the date of delivery to the user.

If any part of the product proves defective under proper and normal use within the warranty period, as the purchaser's exclusive remedy, Datex-Ohmeda will repair or replace, at its sole discretion, the product or any defective part provided it is returned to Datex-Ohmeda Service within 30 days of the failure.

Limitation

Datex-Ohmeda may at any time discharge its warranty obligation by repairing and returning the product to original factory performance. This may be accomplished by installing new or remanufactured assemblies or by other repairs deemed appropriate by Datex-Ohmeda. The choice of repair or replacement by Datex-Ohmeda shall be the sole remedy of the buyer or user.

Conditions

This warranty is valid only when qualified personnel have performed installation and service on the product and when all recommended planned maintenance procedures have been completed during the warranty period. Damage caused by the abuse or misuse of the product is not covered by this warranty. Datex-Ohmeda shall not be liable for damage resulting from the improper installation or the misuse of the product.

Exclusion of warranties

Oral statements about the product do not constitute warranties, shall not be relied on by the buyer or user, and are not part of any warranty extended by Datex-Ohmeda.

Except as set forth in this limited warranty, Datex-Ohmeda makes no warranties, expressed or implied, including the implied warranty of merchantability and the implied warranty of fitness for a particular purpose. Except for the obligations under this limited warranty, Datex-Ohmeda shall not have any obligation or liability for any incidental or consequential damages (including those from commercial loss) or other loss, damage, or injury resulting directly or indirectly from the product.